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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,307	11/27/2000	Emanuel Calenoff	21417/91482	5598

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EXAMINER

ZHOU, SHUBO

ART UNIT

PAPER NUMBER

1631

15

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/723,307

Applicant(s)

CALENOFF ET AL.

Examiner

Shubo "Joe" Zhou

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 2-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicants' amendment and request for reconsideration in Paper #14, filed on 7/9/03, is acknowledged and the amendments entered.

Applicant's arguments in response to the previous Office Action, mailed 1/14/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn. The following rejections and/or objections are reiterated from the previous Office action, and constitute the complete set presently being applied to the instant application.

This application contains claims 2-27 drawn to an invention nonelected with/without traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The rejection of claim 1 under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention in the previous Office action has been withdrawn in view of the amendment to claim 1 in Paper #14.

Claim Rejections-35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 is rejected under 103(a) as being unpatentable over Taylor-Papadimitriou et al. (TIBTECH, June 1994, Vol. 12, pages 227-233) in view of Hopp et al. (Proc. Natl. Acad. Sci. USA, Vol. 78, pages 3824-3828, 1981).

Claim 1 is drawn to a method of identifying candidate cancer-specific or cancer-associated antigen comprising mapping hydrophilic region and identifying sites that are glycosylated in normal cells but de-glycosylated in cancer cells.

Taylor-Papadimitriou et al. disclose a cancer associated antigen MUC1. The protein is a transmembrane protein with an extracellular domain that is hydrophilic. See page 228, Table 1 and left column. Moreover, the domain is glycosylated in normal cells but deglycosylated in breast cancer cells. See page 228, left column, and page 230, right column. Taylor-Papadimitriou et al. further disclose that it is clear that the altered pattern of glycosylation results not only in the appearance of novel carbohydrate epitopes, but also in the unmasking and modification of epitopes in the protein.

Taylor-Papadimitriou et al. further state:

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It has been known for many years that the surface molecules of cancer cells can undergo changes in their glycosylation profile. In recent years, however, these changes have been defined in more detail, and it is now possible to take a more directed approach to exploiting them in the diagnosis and treatment of cancer.

This obviously motivates exploiting the knowledge of the role of glycosylation in cancer diagnosis and treatment. One of ordinary skill in the art would have been motivated to search other proteins/peptides with an altered pattern of glycosylation in cancer cells based on the knowledge with MUC1. While Taylor-Papadimitriou et al. do not explicitly disclose the details of steps (a)-(b) and (e)-(g), those are well-recognized skills in the art. For example, Hopp et al. (Proc. Natl. Acad. Sci. USA, Vol. 78, pages 3824-3828, 1981) teach of a rolling sum analysis of 6 or more consecutive residues to predict antigenic region of a peptide sequence. See page 3826, right column. Therefore, the claimed method would have been obvious to one of ordinary skill in the art at the time the invention was made, and there would have been a reasonable expectation of success for the invention.

This rejection is reiterated from the previous Office action and maintained for reasons of record.

Applicant's arguments filed 7/9/03 have been fully considered but they are not persuasive.

Applicants essentially argue that the references do not disclose mapping hydrophilic region and identifying de-glycosylation site in cancer cells, and there is no motivation to combine the references. This is not found persuasive. As set forth in the previous Office action and above, Taylor-Papadimitriou et al. have discovered an extracellular domain of Mucin containing multiple serine/threonine residues and identified that the domain are glycosylated in normal cells but deglycosylated in breast cancer cells. Moreover, the domain appears to be hydrophilic. See Table 1. Thus, Taylor-Papadimitriou et al. does indeed disclose mapping hydrophilic region and identifying de-glycosylation site in cancer cells.

The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, as set forth above, Taylor-Papadimitriou et al. clearly motivate exploring and searching for cancer antigens containing deglycosylation site for cancer diagnosis and treatment. Further, as set forth in the previous Office action and above, Hopp et al. teach of a method for predicting protein antigenic determinants by using rolling sum and hydrophilicity analysis. Therefore, one of ordinary skill in the art would have been motivated to combine the references of Taylor-Papadimitriou et al. and Hopp et al. to use rolling sum to predict antigenicity in searching for more cancer antigens.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL.


Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. §1.136 (a). A shortened statutory period for response to this final action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136 (a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than six months from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

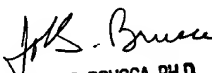
Any inquiry concerning this communication or earlier communications from the examiner should be directed to: Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou, Ph.D. 

Patent Examiner


JOHN S. BRUSCA, PH.D.
PRIMARY EXAMINER